

### **REMARKS/ARGUMENTS**

This Amendment is submitted in response to the non-final Office Action mailed July 23, 2007 (the "Office Action"). Following entry of this amendment, claims 1-14, 17, 19, 20 and 23-27 remain pending in the application. Claims 1, 3 and 23 are independent.

In the Office Action, the Examiner:

- withdrew the indication of allowability of claims 13, 15, 19 and 21 in view of U.S. Patent No. 3,678,925 to Fischer (hereinafter "Fischer");
- withdrew the indication of allowability of claims 6-8 in view of previously cited references;
- objected to the drawings under 37 C.F.R. § 1.83(a) for failing to show every feature of the invention specified in the claims;
- rejected claims 13 and 15 under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement;
- rejected claims 7-9 and 19 under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention;
- rejected claims 1-5, 7, 10-15, 17, 20 and 23-27 under 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. Patent No. 5,454,813 to Lawes (hereinafter "Lawes") in view of Fischer;
- rejected claims 1, 2, 10-13, 17, 19 and 20 under § 103(a) as allegedly being unpatentable over Lawes in view of U.S. Patent No. 2,381,050 to Hardinge (hereinafter "Hardinge"); and
- rejected claims 3-9, 14, 15 and 23-27 under § 103(a) as allegedly being unpatentable over Lawes in view of Hardinge and further in view of U.S. Patent Application Publication No. 2005/0113909 to Shannon (hereinafter "Shannon").

As outlined above, Applicants have amended claims 1,3, 7-9, 13, 19 and 23 to address the objections to the drawings, address the 35 U.S.C. § 112, first and second paragraph rejections, better define the scope of the invention, more clearly distinguish over the cited art, and/or conform with amendments to other claims. Claim 15 has been canceled without prejudice to its subsequent prosecution in any continuing application or disclaimer of the

proprietary rights set forth therein. All amendments are fully supported by the originally-filed specification and/or drawings of the present application. The amendments made herein do not represent acquiescence in the Examiner's rejections, but rather are made only to expedite prosecution of the present application and/or maintain consistency in claim language. Applicants expressly reserve the right to pursue the subject matter of any previously presented claims in one or more continuation applications. As discussed more fully below, Applicants respectfully submit that each of the currently pending claims define features that are not disclosed, taught or suggested by the prior art of record and respectfully request allowance of same.

#### **Drawing Objections**

In the Office Action, the Examiner objected to the drawings for failing to show every feature of the invention specified in the claims. Specifically, the Examiner alleges that the first end of the bone fixation element being configured as a blade as recited in claim 13, is not shown in the figures. In response, as outlined above, Applicants have amended claim 13 to recite that "the first elastically expandable sheath of the bone fixation implant is configured as a blade" as set forth on page 7, lines 17-18 and depicted in Figure 3 of the as-filed application. Accordingly, Applicants respectfully request that the objection to the drawings be withdrawn.

#### **Claim Rejections Under 35 U.S.C. § 112**

Claims 13 and 15 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. The Examiner alleges that the claims contain subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. In response, as outlined above, claim 13 has been amended and claim 15 has been canceled. Accordingly, Applicants respectfully request that the § 112, first paragraph rejections be withdrawn.

In addition, claims 7-9 and 19 are rejected under § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which the Applicant regards as the invention. Specifically, the Examiner asserts that claims 7-9 and 19 contain passive limitations making the claims unclear on whether certain

limitations are necessary for the invention. In response, as outlined above, the recitation "can be" in the claims has been replaced by "is" thereby addressing the Examiner's rejections. Accordingly, Applicants respectfully request that the § 112, second paragraph rejections be withdrawn.

**Claim Rejections Under 35 U.S.C. § 103(a)**

In the Office Action claims 1-5, 7, 10-15, 17, 20 and 23-27 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Lawes in view of Fischer. In addition, claims 1, 2, 10-13, 17, 19 and 20 are rejected under § 103(a) as allegedly being unpatentable over Lawes in view of Hardinge. Lastly, claims 3-9, 14, 15 and 23-27 are rejected under § 103(a) as allegedly being unpatentable over Lawes in view of Hardinge and further in view of Shannon. The rejections are traversed for at least the following reasons.

As recited in revised independent claim 1, the present invention is directed to a bone fixation device comprising, *inter alia*, a bone fixation implant having a

first elastically expandable sheath having a threaded inner surface and formed at the front end of the bone fixation implant, and an expansion agent having a threaded outer surface, wherein the threaded inner surface of the first elastically expandable sheath and the threaded outer surface of the expansion agent engage each other, [and] wherein the expansion agent is capable of moving along the central borehole axis to selectively expand the sheath.

(Emphasis added). Applicants respectfully submit that Lawes, Fischer, Hardinge and Shannon, either alone or in combination, fail to teach such a bone fixation device

In paragraphs 11 and 12 of the Office Action, in rejecting the claims, the Examiner states that there "is no requirement in the claims[s] stating that the expansion agent has an outer surface including threads and the first expandable sheath has an inner surface including threads, wherein the threads of the outer surface of the expansion agent engage the threads of the inner surface of the first expansion sheath . . . ." In response, as outlined above, the claims have been amended to include language similar to that discussed by the Examiner. Accordingly, Applicants respectfully submit that the claims are allowable.

In order to establish *prima facie* obviousness of a claimed invention, the prior art reference or references must teach or disclose all the claim limitations. *M.P.E.P.* § 2143.03 (citing *In re Royka*, 490 F.2d 981 (C.C.P.A. 1974)). Therefore, because the combination of

Lawes, Fischer, Hardinge and Shannon at least fails to teach or disclose a bone fixation device having a "first elastically expandable sheath having a threaded inner surface and formed at the front end of the bone fixation implant, and an expansion agent having a threaded outer surface, wherein the threaded inner surface of the of the first elastically expandable sheath and the threaded outer surface of the expansion agent engage each other," the Section 103 rejections must fail as a matter of law. Accordingly, Applicants respectfully request that the Section 103 rejections be withdrawn.

For at least the foregoing reasons, it is believed that independent claim 1 patentably distinguishes over the relied upon portions of Lawes, Fischer, Hardinge and Shannon, either alone or in combination, and is therefore allowable. Independent claims 3 and 23 are similar in scope to claim 1 and are therefore allowable for similar reasons. Further, claims 2, 4, 10-14, 17, 19 and 20, which depend from claim 1, claims 5-9, which depend from claim 3, and claims 24-27, which depend from claim 3, are allowable as well. Accordingly, Applicants respectfully request that the obviousness rejections be withdrawn, and that the pending claims be allowed.

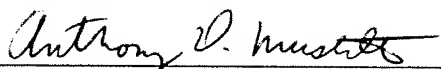
### **CONCLUSION**

In view of the above amendments and remarks, Applicants respectfully request that the Examiner reconsider pending claims 1-14, 17, 19, 20 and 23-27 with a view towards allowance. The Examiner is invited to call the undersigned attorney at (212) 326-3939 if a telephone call could help resolve any remaining issues.

Should any additional fees be required by reason of this Amendment, please charge such fees to Jones Day deposit account no. 50-3013.

Respectfully submitted,

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